K101635

AUG 3 1 2011

510 (k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
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Date Prepared	June 7th, 2010

2. Name of Device

Trade/Proprietary Name	TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System
Common Names	Blood glucose test system
Product Code	NBW, LFR
Classification Panel	Clinical Chemistry (75)
Regulations	Class II 21 CFR 862.1345

3. Predicate Device

Trade/Proprietary Name:	FORA G31 Blood Glucose Monitoring System (Model TD-4256)
Common/Usual Name:	Blood glucose test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K094005

4. Device Description

The TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System consist of three main products: the meter, test strips and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only TD-4239 and TD-4239 Multi test strips for the TD-4239 and TD-4239 Multi Blood Glucose Monitoring Systems, and use with the control solutions that has been tested and validated with this system to perform quality checks.

The blood glucose detection method and measurement is by an electrochemical biosensor technology using FAD-dependent glucose dehydrogenase (FAD-GDH).

The two blood glucose systems have the same technical components (same meter and test strips) and therefore the same performance data.

5. Intended Use

For single use device

The TD-4239 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.
The TD-4239 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates.

The TD-4239 Blood Glucose Test Strips are for use with the TD-4239 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

For multiple patient use device

The TD-4239 Multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary, venous and neonatal whole blood samples. The TD-4239 Multi Blood Glucose Monitoring System is intended for testing outside the body (*in vitro* diagnostic use) and is intended for multiple patient use in professional healthcare settings as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus.

Professionals may test with capillary, venous and neonatal whole blood. Capillary samples may be drawn from the fingertip, and in the case of neonates, from the heel.

The system is only used with single-use, auto-disabling lancing devices.

The TD-4239 Multi Blood Glucose Test Strips are for use with the TD-4239 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary, venous and neonatal whole blood samples.

6. Comparison to Predicate Device

The TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System have the same operating principle and same fundamental scientific technology as FORA G31 Blood Glucose Monitoring System (K094005). Modifications include test strip change, meter outer casing design, and software modifications. Accuracy study and software validation were performed to evaluate the meter performance. Results show that both devices are substantially equivalent to the predicate device K094005.

7. Performance Studies

The laboratory and clinical studies for the system performance of TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System demonstrate the meter and test strip works well as a system.

Software verification and validation tests confirmed that the performance, safety and effectiveness of the TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion

The TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System demonstrate satisfactory performance. The TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System are therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 31 2011

Taidoc Technology Corporation
c/o Teling Hsu
3f,5f, No.127 Wugong 2nd Rd,
Wugu Township
Taipei County
Taiwan 24888

Re: K101635
Trade name: TD-4239 Blood Glucose Monitoring System
TD-4239 Multi Blood Glucose Monitoring System
Regulation Number: 21CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: August 25, 2011
Received: August 29, 2011

Dear Ms. Hsu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Attachment C4

Indications for Use

510(k) Number: k101635

Device Name: TD-4239 Blood Glucose Monitoring System

Indications for Use:

The TD-4239 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

The TD-4239 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates.

The TD-4239 Blood Glucose Test Strips are for use with the TD-4239 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

Prescription Use _____	AND/OR	Over the Counter Use __X__
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number: k101635

Device Name: TD-4239 Multi Blood Glucose Monitoring System

Indications for Use:

The TD-4239 Multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary, venous and neonatal whole blood samples. The TD-4239 Multi Blood Glucose Monitoring System is intended for testing outside the body (*in vitro* diagnostic use) and is intended for multiple patient use in professional healthcare settings as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus.

Professionals may test with capillary, venous and neonatal whole blood. Capillary samples may be drawn from the fingertip, and in the case of neonates, from the heel.

The system is only used with single-use, auto-disabling lancing devices.

The TD-4239 Multi Blood Glucose Test Strips are for use with the TD-4239 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary, venous and neonatal whole blood samples.

Prescription Use __X__	AND/OR	Over the Counter Use __X__
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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